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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,624	02/04/2002	Roberto Valducci	242/9-1646	4252

7590

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EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/067,624

Applicant

Valducci

Examiner

PaK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 10-18 is/are withdrawn from consideration
- 5) ☒ Claim(s) 1-3 is/are allowed.
- 6) ☒ Claim(s) 4-8 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

Art Unit: 1616

Claims 1-18 are pending in this application.

Restriction to one of the following inventions is required under 35 USC 121:

- I. Claims 1-9, drawn to a multiparticulate formulation of lithium.
- II. Claims 10-18, drawn to a process for preparing a multiparticulate formulation of lithium.

The two inventions are distinct, because the multiparticulate can be made by a materially different process, such as by precipitation or spray coating directly and then sizing.

To examine more than one invention would place an undue burden on the Examiner because the search and review of the prior art relevant to the formulation per se is already of considerable task. The prior art for lithium formulations is quite extensive and not necessarily pertinent to process of preparing or techniques of preparing. To have to search in divergent fields to meet the process features, given the substantial burden that is already present in the composition search and review, would place a serious and undue burden on the Examiner.

Therefore, for the reasons of distinctness and undue burden, the restriction requirement as set forth above is deemed to be proper.

During a telephone conversation with Mr. Sapone on 6/24/03, a provisional election with traverse was made to prosecute the invention of Group I, claims 1-9. Affirmation of this election must be made by applicant in replying to this Office Action. Claims 10-18 are withdrawn from further consideration as being directed to non-elected subject matter.

Art Unit: 1616

Claims 4-8 rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites a dissolution profile. However, a dissolution profile without additional parameters is meaningless. Dissolution is affected by various factors such as solvent, pH, temperature, shape and makeup of the dissolving substance, etc. None of such parameters are provided in claim 4.

In claims 5, 6 and 8, the accepted Markush language for listing alternative compounds is, "selected from the group consisting of ... and ...." Certain variations are also accepted, but applicant's "chosen from the group including" is not sufficient. The group is not clear in what else it may include.

Claim 7 recites trademarks. A trademark is a designation for a source of a substance, not a name for the actual substance itself.

Claims 1-3 are allowed.

Claim 9 is objected to as being dependent on a rejected claim. Claim 9 would be allowed if rewritten to include the claim limitations and features of the base claim and any intervening claim(s).

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Serial Number: 10/067,624


-4-

Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600